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**UNITED STATES DEPARTMENT OF COMMERCE****Patent and Trademark Office**

Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/704,299 11/01/00 BIANCHI

J RTI-106

EXAMINER

QM32/0830

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PHILIPGENE, P

ART UNIT

PAPER NUMBER

3732

DATE MAILED:

08/30/01

5

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)	
09/704,299	BIANCHI ET AL.	
Examiner	Art Unit	
Pedro Philogene	3732	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 01 November 2000.

2a) This action is FINAL. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-23 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 1-23 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>04</u> .	6) <input type="checkbox"/> Other: _____

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 6, 7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 6, 7, line 1, the term "said wedge shape" lacks prior antecedent.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 1-4, 9, 17-22 are rejected under 35 U.S.C. 102(e) as being anticipated by Boyle et al. (6,277,149).

With respect to claim 1, Boyle et al. disclose a biomedical implant (10) designed for implantation into a spine of a patient comprising an elongated body (12) having first and second ends (FIG.1), the elongated body being tapered such that tapering begins at a first position on or proximate to the first end and continues down the length of the elongated body down to a second position on or proximate to the second end; as best seen in FIGs.1, 3, 9; wherein the implant is comprised of cortical or cancellous bone; as set forth in column 2, lines 40-45.

With respect to claims 2-4, 9,17-19 Boyle et al discloses all the limitations, as set forth.

With respect to claims 20-23, the method steps, as set forth, would have been inherently carried out in the operation of the device, as set forth above.

Claims 15,16 are rejected under 35 U.S.C. 102(e) as being anticipated by Rainey et al (6,111,164).

With respect to claims 15,16, Rainey et al. disclose a method of producing a biomedical implant (10) that comprises an elongated body (12) having first and second ends (FIG.1) wherein the first end comprises two or more oblique sides (18), the method comprising obtaining a bone having a ridge naturally formed thereon and excising bone block sections from the bone at an angle substantially perpendicular to the ridge; as best seen in FIGS. 2A-2C; and as set forth in column 2, lines 57-67 and column 3, lines 1-15.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 5-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boyle et al. (6,277,149) in view of Rainey et al. (6,111,164).

With respect to claims 5-8, it is noted that Boyle et al did not teach of an implant defining a wedge shape and having pinch cuts out in the first end formed

thereon; as claimed by applicant. However, in a similar art, Rainey et al. evidence the use of a dowel with pinch cut outs in the first end, defining a wedge edge to facilitate the positioning of the dowel into a bone opening for grafting.

Therefore, given the teaching of Rainey et al, it would have been obvious to one having ordinary skill in the art at the time the invention was made to incorporate the wedge shape of Rainey et al in the device of Boyle et al., to facilitate the positioning of the dowel into a bone opening for grafting.

Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Boyle et al. (6,277,149) in view of Branch et al (6,174,311).

With respect to claim 10, it is noted that Boyle et al. did not teach of an implant having a peg portion in the first end to engage a securing device, as claimed by applicant. However, in a similar art, Branch et al, column 10, lines 48-65, evidence the use of peg portion for securely engaging a tool holder.

Therefore, given the teaching of Branch et al, it would have been obvious to one having ordinary skill in the art at the time the invention was made to incorporate the peg portion of Branch et al in the device of Boyle et al for securely engaging a tool holder.

Claims 11-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boyle et al. (6,277,149) in view of Paul et al (6,258,125).

With respect to claims 11-14, it is noted that Boyle et al teach all the limitations, except for an implant comprising two separate sections, as claimed by applicant. However, in a similar art, Paul et al, as best seen in FIGS 7,9,11, and column 4, lines

40-57, evidence the use of an implant having two separate sections to allow smaller sections of allergenic bone to be used for the fabrication of an implant.

Therefore, given the teaching of Paul et al, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use the method of Paul et al to fabricate the device of Boyle et al to allow smaller sections of allergenic bone to be used for the fabrication of the implant.

Drawings

Color photographs and color drawings are acceptable only for examination purposes unless a petition filed under 37 CFR 1.84(a)(2) or (b)(2) is granted permitting their use as formal drawings. In the event applicant wishes to use the drawings currently on file as formal drawings, a petition must be filed for acceptance of the photographs or color drawings as formal drawings. Any such petition must be accompanied by the appropriate fee as set forth in 37 CFR 1.17(i), three sets of drawings or photographs, as appropriate, and an amendment to the first paragraph of the brief description of the drawings section of the specification which states:

The file of this patent contains at least one drawing executed in color. Copies of this patent with color drawing(s) will be provided by the Patent and Trademark Office upon request and payment of the necessary fee.

Color photographs will be accepted if the conditions for accepting color drawings have been satisfied.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Art Unit: 3732

5,593,409 1-1997 Michelson

6,165,219 12-2000 Kohrs et al.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pedro Philogene whose telephone number is (703) 308-2252. The examiner can normally be reached on Monday to Friday 6:30 AM to 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gene Mancene can be reached on (703) 308-2696. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3579 for regular communications and (703) 305-3591 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

Pedro Philogene
August 28, 2001


PEDRO PHILogene
PRIMARY EXAMINER

Attachment for PTO-948 (Rev. 03/01, or earlier)
6/18/01

The below text replaces the pre-printed text under the heading, "Information on How to Effect Drawing Changes," on the back of the PTO-948 (Rev. 03/01, or earlier) form.

INFORMATION ON HOW TO EFFECT DRAWING CHANGES

1. Correction of Informalities -- 37 CFR 1.85

New corrected drawings must be filed with the changes incorporated therein. Identifying indicia, if provided, should include the title of the invention, inventor's name, and application number, or docket number (if any) if an application number has not been assigned to the application. If this information is provided, it must be placed on the front of each sheet and centered within the top margin. If corrected drawings are required in a Notice of Allowability (PTOL-37), the new drawings **MUST** be filed within the **THREE MONTH** shortened statutory period set for reply in the Notice of Allowability. Extensions of time may NOT be obtained under the provisions of 37 CFR 1.136(a) or (b) for filing the corrected drawings after the mailing of a Notice of Allowability. The drawings should be filed as a separate paper with a transmittal letter addressed to the Official Draftsperson.

2. Corrections other than Informalities Noted by Draftsperson on form PTO-948.

All changes to the drawings, other than informalities noted by the Draftsperson, **MUST** be made in the same manner as above except that, normally, a highlighted (preferably red ink) sketch of the changes to be incorporated into the new drawings **MUST** be approved by the examiner before the application will be allowed. No changes will be permitted to be made, other than correction of informalities, unless the examiner has approved the proposed changes.

Timing of Corrections

Applicant is required to submit the drawing corrections within the time period set in the attached Office communication. See 37 CFR 1.85(a).

Failure to take corrective action within the set period will result in **ABANDONMENT** of the application.